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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Robert J. Linhardt

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05/16/2006

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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



**DETAILED ACTION*****Drawings***

The drawings are objected to because Figure 5, which shows a graph for tumor volume versus days does not have a legend as to what the dark and clear circles and triangles represent. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

Claims 11-20 are objected to because of the following informalities: Claims 16-20 are duplicates of claims 11-15. Claims 16-20 have to be cancelled. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bernfield et al (US 6,028,061).

Bernfield et al teach a pharmaceutical composition comprising acharan sulfate (which has the structural formula recited in instant claims 11 and 16). The acharan sulfate comprises of monomers ranging from 6-50 monomer units (col. 12, lines 1-5; co. 3, line 62 through col. 4, line 10; col. 4, line 46 through col. 5, line 56; col. 9, lines 36-36). This teaching meets the limitations of instant claims 11-20.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bernfield et al (US 6,028,061) in combination with Zetter (Annu. Rev. Med. 1998, 49, 407-24).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is drawn to a method of treatment of cancer using acharan sulfate (formula recited in claim 1) and dependent claims 2-5 recite the number of repeating units in the formula. Claim 6 is drawn to a method of inhibiting an increase in the volume of a mass of tumor using acharan sulfate (formula recited in claim 6) and dependent claims 7-10 recite the number of repeating units in the formula.

Bernfield et al teach that glycosaminoglycans like acharan sulfate inhibit angiogenesis and that it can be used in treatment of diseases that are angiogenesis dependent (col. 2, 58-67). The acharan sulfate used in Bernfield's invention can have about 6-50 monomer repeat units and is formulated into a pharmaceutical composition (col. 3, line 62 through col. 5, line 55).

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According to Bernfield, excessive blood vessel proliferation can result in tumor growth and tumor spread (col. 1, lines 45-50 and col. 3, lines 1-6). However, Bernfield does not specifically teach that cancer is associated with blood vessel proliferation.

Zetter teaches that angiogenesis has been implicated in human cancer (page 409, middle paragraph).

From the teachings of Bernfield and Zetter, one of ordinary skill in the art will understand that inhibiting angiogenesis is an art recognized way of treating cancer and tumor, including tumor volume reduction. Bernfield also teaches the inhibition of angiogenesis using acharan sulfate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat cancer and inhibit an increase the volume or mass of a tumor by administering an effective amount of a compound as instantly claimed, with a reasonable amount of success since such is seen to be taught in the prior art.

One of ordinary skill in the art would be motivated to use a compound as instantly claimed in a method treating cancer and in a method of inhibiting the volume or mass of a tumor since acharan sulfate has a very low toxicity (Bernfield, col. 2, lines 54-64).

### ***Conclusion***

Claims 1-20 are rejected

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

A handwritten signature in black ink, appearing to read 'SAJ 5/10/06', is written over a horizontal line.

Shaojia A. Jiang  
Supervisory Patent Examiner  
Art Unit 1623